IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

TERESA HARPER, as legal guardian of CLINTON HARPER,	)	
Plaintiff,	)	
v.	)	**Case No. 2:17-cv-603-WKW-DAB**
JANSSEN PHARMACEUTICALS, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this pharmaceutical products liability case, Plaintiff Teresa Harper, as legal guardian of Clinton Harper,[1] sues Defendant Janssen Pharmaceuticals, Inc.,[2] alleging her son's ingestion of Risperdal caused her son to develop gynecomastia, an abnormal development of breasts in males. Pending before the court are the Motion for Summary Judgment by Janssen (Doc. 12), Plaintiff's Motion to Exclude Certain Testimony by Janet Arrowsmith, M.D., (Doc. 3), Plaintiff's Motion to Exclude Certain Testimony by Elias G. Chalhub, M.D. (Doc. 5), Defendant's Motion to Preclude Expert Testimony by Michael D. Freeman, MedDr, MPH, FAAFS (Doc. 14), Defendant's Motion to Preclude Expert Testimony of Laura M. Plunkett, PhD, DABT (Doc. 16), and Defendant's

[1] The case was initially filed with co-Plaintiff, Patricia West, as legal guardian of LaQuinton West, whose claims have since been severed. *See* Docs. 1; 34-2 at 13–69; *see also* Doc. 1-13 in Case No: 2:15-cv-553-WKW-DAB.

[2] Plaintiff's initial complaint sued Janssen Pharmaceuticals, Inc. also known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Ortho-McNeil Pharmaceutical Products, Inc.; Janssen, LP formerly known as Janssen Pharmaceutica Products LP; Johnson & Johnson; Janssen Research and Development, LLC, formerly known as Johnson & Johnson Research and Development, LLC; Dana Michele King; Preston Jerome Byrd; Patty Mims Funkhauser; Mindy L. Basquin; and John Does 1–50. *See* Doc. 34-2. Janssen Pharmaceuticals, Inc. is the only remaining Defendant in the case.

Motion to Preclude Expert Testimony of Elizabeth Z. Naftalis, M.D. (Doc. 18). The parties filed sealed and unsealed joint exhibits in support, *see* (Doc. 34), and have had the opportunity to fully brief the motions. *See* Docs. 4, 6, 13, 15, 17, 19, 20, 22, 24–33.[3] The court requested additional briefing on the Eleventh Circuit's recent opinion in *Small v. Amgen, Inc*., et al., No. 17-11440, 2018 WL 501354 (11th Cir. Jan. 22, 2018). (Docs. 35–37). For the reasons that follow, it is recommended that the Motion for Summary Judgment by Janssen (Doc. 12) be **granted** and the *Daubert* motions (Docs. 3, 5, 14, 16, 18) be **denied as moot**.

I. JURISDICTION

Janssen Pharmaceuticals, Inc.[4] ("Janssen") removed the initial case to this court pursuant to 28 U.S.C. § 1332 on the basis of diversity of citizenship and an amount in controversy in excess of seventy-five thousand dollars.[5] *See* Case No: 2:15-cv-553-WKW-DAB, Doc. 1. Plaintiff dismissed the individual Defendants, some of whom were non-diverse. *Id.* at Doc. 13. The only remaining Defendant is Janssen Pharmaceuticals, Inc. The parties do not contest personal jurisdiction or venue, and the court finds sufficient information of record to support both. *See* 28 U.S.C. § 1391. On January 5, 2017, the case was referred to the undersigned for recommendation on all pretrial matters; *see also* 28 U.S.C. § 636(b); Rule 72, Fed. R. Civ. P.; *United States v. Raddatz*, 447 U.S. 667 (1980).

II. LEGAL STANDARD

[3] Additionally, Janssen filed supplemental authority (Doc. 38) in support of its Motion to Preclude Expert Testimony of Laura Plunkett on the preemption issue, but it is not pertinent to the analysis due to the court's recommendation summary judgment be granted on other issues.

[4] Effective December 31, 2007, Janssen Pharmaceutica, Inc. changed its name to Ortho-McNeil-Janssen Pharmaceuticals, Inc. On June 22, 2011, Ortho-McNeil-Janssen Pharmaceuticals, Inc. changed its name to Janssen Pharmaceuticals, Inc. (Doc. 12, n.1).

[5] Janssen acknowledges that Plaintiff meets the jurisdictional amount in controversy for purposes of diversity jurisdiction. *See* Case No: 2:15-cv-553-WKW-DAB at Doc. 1, n.5.

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the Court construes the facts and all reasonable inferences therefrom in the light most favorable to the nonmoving party. *Reeves v. Sanderson Plumbing Prods., Inc*., 530 U.S. 133, 150 (2000). However, when faced with a "properly supported motion for summary judgment, [the nonmoving party] must come forward with specific factual evidence, presenting more than mere allegations." *Gargiulo v. G.M. Sales, Inc.*, 131 F.3d 995, 999 (11th Cir. 1997).

Summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "Summary judgment may be granted if the non-moving party's evidence is merely colorable or is not significantly probative." *Sawyer v. Southwest Airlines Co*., 243 F. Supp. 2d 1257, 1262 (D. Kan. 2003) (citing *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 250–51 (1986)).

"[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. "Essentially, the inquiry is 'whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Sawyer*, 243 F. Supp. 2d at 1263 (quoting *Anderson*, 477 U.S. at 251–52).

III. BACKGROUND FACTS

Teresa Harper ("Plaintiff") is the mother and legal guardian for her son, Clinton Harper ("Harper"). *See* Doc. 34-2 at 13–69. Plaintiff filed this lawsuit against Janssen related to the

design, manufacture, sale, marketing, advertising, promotion, and distribution of Risperdal.[6] *Id.*, ¶ 1. She alleges that Harper ingested Risperdal and suffered injuries as a result, including a condition called gynecomastia,[7] abnormal development of breasts in males. *Id.*, ¶ 2–4. Plaintiff asserts claims against Janssen for failure to warn under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") (Count I), negligence (Count II), wanton misconduct (Count III), failure to warn (Count IV), breach of implied warranty of merchantability (Count V), fraud (Count VIII), and negligent misrepresentation (Count IX).[8] The facts, viewed in a light most favorable to Plaintiff as the non-moving party, are as follows:

A. Harper's Risperdal Use

Harper was born in June 1990. *See* Docs. 34-87 at 5, 34-91 at 3; *see also* Doc. 16-1 in Case No: 2:15-cv-553-WKW-DAB. He was four and one-half year's old when he was diagnosed with autism. (Doc. 34-86 at 132:15–18). Harper started taking Risperdal, prescribed by Dr. Jan Mathisen, sometime between 1995 and 1996 at the age of five or six. (Doc. 34-87 at 18–19). Treatment records from June 19, 1996, revealed Dr. Mathisen had been seeing Harper since 1995. *Id.* at 18:15–17.[9] Harper was seen for an assessment on this date through the developmental clinic at UAB School of Medicine. *Id.* at 16–17. His medications at the time were clonidine and Risperdal. *Id.* at 18:18–19:3. Growth parameters revealed he gained too much weight within the last few months. *Id.* at 19:12–22. He was Tanner Stage I, meaning prepubertal. *Id.* at 20:3–11.

[6] The case was filed in state court, but removed to this court by Janssen.

[7] *See* (Doc. 34-4).

[8] Plaintiff had also asserted claims for breach of express warranty (Count VI), breach of implied warranty of fitness for a particular purpose (Count VII), and civil conspiracy (Count X), but the court entered summary judgment in Janssen's favor on those claims based on Plaintiff's concessions. *See* (Doc. 1).

[9] When Dr. Mathisen was deposed, he indicated he could not locate his medical records showing when he began and stopped treating Harper, nor could he find records concerning his care, evaluation and treatment of Harper. (Doc. 34-87 at 12, 22–23, 85).

The primary problem identified was macrocephaly and accelerated growth not explained by his autism. *Id.* at 20:12–21:4. The second problem identified was Harper's medication, noting he was on a combination of Risperdal and clonidine. *Id.* at 23–24. The records reflect the potential side effect of dyskinesia which can occur from prolonged use of an antipsychotic drug; the records make no mention of gynecomastia as a side effect. *Id.* at 25:3–14. Dr. Zachor, who authored the note, suggested reconsidering the use of antipsychotic drugs. *Id.* at 25:15–19. Dr. Mathisen had no recollection of discussions with Dr. Zachor regarding Harper's treatment or the discontinuation of antipsychotic drugs. *Id.* at 26, 32.

Dr. Parrott prepared a new patient evaluation of Harper on September 24, 1996. *Id.* at 26. The records reflect an MRI performed in June 1996 showed a benign cyst in Harper's brain. *Id.* at 27–28. The MRI revealed underdeveloped white matter that is often associated with certain forms of developmental delay and also showed a loss of brain tissue known as encephalomalacia. *Id.* at 29–30. A follow-up visit is referenced in a March 11, 1997, letter from Dr. Parrot to Dr. Zachor. *Id.* at 34. Harper had a positive Berry spot test, and a repeat CT scan to evaluate the pineal cyst showed it was stable with no further growth. *Id.* at 34–35.

Pediatric endocrinologist, Dr. Hussein Abdul-Latif performed a physical examination of Harper on November 27, 2000. (Doc. 34-91 at 8). Harper's medications at the time included Risperdal, and his mother expressed concern about his weight gain. *Id.* Dr. Abdul-Latif noted "some evidence of gynecomastia in his chest." *Id.* at 6. Dr. Abdul-Latif's examination revealed Harper, who was ten years old at the time, was a Tanner Stage I prepubescent male *Id.* Prolactin levels were at 27, which Dr. Abdul-Latif indicated was high. *Id.* The doctor's assessment was a pituitary adenoma and type II diabetes. *Id.* at 6–7.

Dr. Abdul-Latif saw Harper again on September 8, 2004. *Id.* at 3–5. Harper was not taking Risperdal at the time. Dr. Abdul-Latif ordered bloodwork, including checking his prolactin level, which was normal. *Id.* at 4.

On August 31, 2016, Dr. April Maddux examined Harper and performed a breast examination. (Doc. 34-94). She had his prolactin level tested again, and it was normal. *Id.* Dr. Maddux performed the breast examination using two different methods to determine whether Harper had gynecomastia. (Doc. 34-102 at 51:6–53:18). Based on her examinations, Dr. Maddox diagnosed Harper with Grade 4 bilateral gynecomastia. *Id.* at 20–23, 67–68.

According to Harper's medical records, Dr. Mathisen was the initial prescriber of Risperdal. (Doc. 25 at 4). Pharmacy records show Dr. Mathisen prescribed Risperdal for Harper starting in September 1996 with a final prescription written by Dr. Mathisen in November 1999. *See* Docs. 34-90, 34-111. Dr. David Hall and Dr. Azarcon wrote Risperdal prescriptions for Harper between November 1999 and November 2000.[10] *Id.* It appears that November 2000 was the last time Harper was prescribed Risperdal. (Doc. 34-86 at 299:3–12).

Dr. Hall also had no records for Harper and did not recall treating him. (Doc. 34-89 at 15). He was able to identify the prescriptions he wrote for Harper through the pharmacy records, but did not recall the reason for prescribing Risperdal or what he was treating Harper for. *Id.* at 56.

Plaintiff states she consented to her son's use of Risperdal based on Dr. Mathisen's recommendation, but claims she would not have agreed if she had been told Risperdal can cause gynecomastia. (Doc. 34-68). It is undisputed that Risperdal improved Harper's behavior and

[10] On cross examination of Dr. Mathisen, the defense demonstrated the pharmacy records contained numerous errors, including associating Dr. Mathisen's name with a DEA number that was not his, a prescription of sixty one-milligram Risperdal tablets for ten days (or 6 milligrams per day), which would be excessive for a six-year-old boy, and a 25-day supply of Risperdal being filled five days after a prescription for a 25-day supply was filled. (Doc. 34-87 at 95–103).

provided a benefit. (Doc. 34-86 at 176–78). Following his Risperdal use, Harper took a number of different medications, but none was as satisfactory as Risperdal, until Harper began taking Abilify, which he took from March 2004 until at least Plaintiff's deposition in July 2016. *Id.* at 223, 308–09. Abilify is used to control Harper's behavior and is associated with weight gain. *Id.* at 224–25. Plaintiff testified that she allowed Harper to continue to use Abilify even though she was advised that Abilify was "harmful to him" and one physician stated that Abilify "was killing [her] son." *Id.* at 226–28. Harper gained over 100 pounds after discontinuing Risperdal in November 2000. *Compare* Doc. 34-91 at 8, *with* Doc. 34-91 at 3.

B. 1993 and 2006 Risperdal Labels

The 1993 Risperdal label contained the following information in the "precautions" section:

> Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. … Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds, the clinical significance of elevated serum prolactin levels is unknown for most patients.

(Doc. 34-97). The 1993 label additionally noted that gynecomastia had been reported in pre-marketing clinical trials:

> Other Events Observed During the Pre-marketing Evaluation of RISPERDAL
> …
> *Endocrine Disorders: Rare:*[11] gynecomastia, male breast pain, antidiuretic hormone disorder.

(Doc. 34-97 at 6). The above language from the 1993 Risperdal label continued to be contained in the Risperdal labels until October 2006. *See* Docs. 34-54–34-67. During these years, the Risperdal label stated that "Safety and effectiveness in children have not been established." *See id.* In July 1998, in the "Dosage and Administration" section of the Risperdal label, the following

[11] "Rare" is defined in the Risperdal label as occurring in fewer than 1 in 1000 patients. (Doc. 34-97 at 6).

language was added: "**Pediatric Use:** Safety and effectiveness in pediatric patients have not been established." (Doc. 34-98 at 10).

In 1996, Janssen added a section to the label concerning adverse events since market introduction which were temporally (but not necessarily causally) related to Risperdal. Up until October 2006, the section never included a reference to gynecomastia being an adverse event. *See, e.g.*, Docs. 34-54–34-67.

The October 2006 Risperdal label added and deleted certain language as it relates to hyperprolactinemia. Specifically, the reference to the "clinical significance of elevated serum prolactin levels is unknown for most patients" was deleted in the October 2006 version. *Compare* Doc. 34-97, *with* Doc. 34-99. The revised language contained in the "precautions" section stated:

> Hyperprolactinemia
> As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. … Galactorrhea, amenorrhea, gynecomastia and impotence have been reported in patients receiving prolactin-elevating compounds.

(Doc. 34-99 at 4). The October 2006 Risperdal label included the following language regarding pediatric use and the risk of gynecomastia for children/adolescents:

> The efficacy and safety of RISPERDAL in the treatment of irritability associated with autistic disorder were established in two 8-week, placebo-controlled trials in 156 children and adolescent patients, aged 5 to 16 years.
> …
>
> Hyperprolactinemia, Growth, and Sexual Maturation
> Risperidone has been shown to elevate prolactin levels in children and adolescents as well as in adults.
> …
> In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorders treated with risperidone, galactorrhea was reported in 0.8% of risperidone-treated patients and gynecomastia was reported in 2.3% of risperidone-treated patients.

(Doc. 34-99 at 5).

C. Janssen Studies and Knowledge of Risks Prior to 2006 Label Change

In December 1994, Janssen conducted a Risperdal taskforce examining the strengths and weaknesses of Risperdal versus competitors' drugs. (Doc. 34-123). High prolactin increase was listed as a Risperdal weakness, *id.* at 8, compared to Sertindole which had a strength of no prolactin increase, *id.* at 6, Seroquel had low prolactin increase, *id.* at 5, and Olanzapine had limited prolactin increase, *id.* at 4. In July 1997, Janssen conducted a "Risperdal National Advisory Board" meeting in which Janssen recognized Ziprasidone's "prolactin increase is less than observed with Risperdal," and "prolactin increase does produce related-side effects regardless of what Integrated Safety Base data shows." (Doc. 34-124 at 3). In August 1997, Janssen prepared a 1998 Business Plan recognizing that Olanzapine, Quetiapine, and Sertindole had "low prolactin," and that "prolactin elevation" was a weakness for Risperdal. (Doc. 34-125 at 3–4). In September 1997, the FDA rejected an attempt by Janssen to include dosing recommendations in the Risperdal label for children and adolescents. (Doc. 34-126). In December 1998, Janssen presented a comparison of risperidone and olanzapine to the American College of Neuropsychopharmacology in which it was acknowledged that gynecomastia is an adverse event "definitely causally related to serum prolactin." (Doc. 34-127 at 2–3).

From May 1997 until October 1998, Janssen conducted a study of risperidone use in children aged 5 to 12 years. (Doc. 34-128). The November 2000 report on the study showed a 12.7% rate for hyperprolactinemia in the children treated with risperidone. *Id.* at 3. In a risperidone study of children aged 5 to 12 years conducted from September 1997 until July 1999, Janssen reported in November 2000 that the study revealed an 11.3% rate for hyperprolactinemia in the children and adolescents treated with risperidone.[12] (Doc. 34-129 at 2–5). In September

[12] No subject in the risperidone group and one subject in the placebo group reported prolactin-related adverse events (dysmenorrhea). (Doc. 34-129 at 4).

1999, Janssen reported on a study comparing risperidone and olanzapine which demonstrated a hyperprolactinemia rate of 7.1% for risperidone users compared to 0.0% for olanzapine subjects. (Doc. 34-130 at 7). In a September 2003 report, Janssen admitted that "[e]levated prolactin plasma levels can directly induce galactorrhea and gynecomastia," and in long-term phase III trials, 3.7 % of males reported gynecomastia. (Doc. 34-131 at 3).

In a 2003 article titled *Prolactin Levels During Long-Term Risperidone Treatment in Children and Adolescents*, *see* (Doc. 34-133), the authors noted "[n]o correlation was found between SHAP [side effects hypothetically attributable to prolactin] and prolactin levels, even when male gynecomastia during puberty was included." *Id.* at 8. Plaintiff has proffered communications between the article authors and Janssen representatives, prior trial testimony of the authors, and drafts of the manuscript to demonstrate Janssen was aware of a statistically significant relationship at usage for 8 to 12 weeks between SHAP and prolactin levels, which directly contradicted the article's representation of no correlation. (Doc. 25 at 15–16).

D. Knowledge of Prescribing Physicians

1. Dr. Mathisen

Dr. Mathisen did not have a specific recollection of Harper or Plaintiff, nor any recollection of the treatment he provided to Harper or any conversations he had concerning risks associated with the medications he recommended. (Doc. 34-87 at 21–22). Dr. Mathisen testified he knew that safety and effectiveness in pediatric patients had not been established with Risperdal use prior to 2006 and took that fact into account when prescribing Risperdal to his pediatric patients. *Id.* at 104:5–15. Although he could not recall specific discussions with Plaintiff regarding risks and benefits of Risperdal, Dr. Mathisen's custom and practice before Risperdal received an indication for pediatric use would be to tell parents of children and adolescents that the safety and effectiveness had not been established. *Id.* at 105:16–106:21. Dr. Mathisen testified that he would

explain to parents that the use of the medication is off-label,[13] meaning that it was not an FDA-recommended management. *Id.* If a parent objected to using the medication off-label, Dr. Mathisen would not use it. *Id.* at 107.

Dr. Mathisen understood the Risperdal label advised physicians who elected to use the medication with patients for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient, and he took this into account in making his prescribing decision. *Id.* at 109–10. It would be Dr. Mathisen's practice to continue a patient on a medication if he felt the benefits outweighed the risks. *Id.* at 117. Given the fact that Harper was continued on Risperdal, Dr. Mathisen testified that indicates he reached a medical judgment that Risperdal was providing a therapeutic benefit to Harper. *Id.* at 118. According to Dr. Mathisen, "[b]ased on the continuation [of the medication], any side effects that the family may have been concerned about, obviously we felt we could deal with and just continue the medication." *Id.* at 119:1–4. If Dr. Mathisen had been prescribing the medication for three years and Plaintiff had complained to him about Harper's excessive weight gain or growth, he testified that they would have discussed it.[14] *Id.* at 121. He was aware when he began prescribing Risperdal in 1996 for Harper that Risperdal was associated with weight gain, and he took that into account in prescribing the medication. *Id.* at 129.

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[13] An off-label use can include "prescriptions of the drug for a condition not indicated on the label, treating an indicated condition at a different dose or frequency than specified on the label, or treating a different patient population than approved by the FDA." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1356 n.4 (11th Cir. 2011). Off-label use of a prescription medicine is lawful. "Once a drug has been approved by the FDA and placed on the market, physicians may prescribe it for *any* purpose. The use of a drug 'off-label' is therefore common in and accepted as beneficial by the health care community." *Id.* (emphasis in original).

[14] Dr. Mathisen testified that excessive height and weight gain would not be attributable to Risperdal use in his opinion, but rather would be more consistent with a pituitary adenoma or Sotos syndrome. (Doc. 34-87 at 122).

As of October 2006, Dr. Mathisen had treated over one thousand patients with Risperdal without any patient experiencing gynecomastia as a side effect. (Doc. 34-87 at 517:18–518:7). If he had seen something unusual, he would have spent more time looking at the package insert regarding it. *Id.* at 518:7–13. Dr. Mathisen was aware that gynecomastia was a potential side effect of prolactin-elevating compounds independent of what was contained in the label. That was something he knew through his medical education and experience and took it into account when he prescribed Risperdal. *Id.* at 423:2–425:4. Dr. Mathisen testified that if he had known that Risperdal elevated prolactin levels more than other second-generation antipsychotics, he would have factored that into his analysis and discussed with his patient's parents. (Doc. 34-116 at 252–53).

2. Dr. Hall

Dr. Hall does not recall Harper or his treatment of him. (Doc. 34-89 at 52). Prior to prescribing medication to his patients, Dr. Hall testified that he would conduct a risk/benefit analysis. *Id.* at 38:5–10. He would then discuss the risks and benefits of the medication with the patient or the patient's parent or guardian. *Id.* at 38:13–39:7. Dr. Hall does not recall any discussions with Plaintiff about the risks and benefits of Risperdal. *Id.* at 69. While Dr. Hall hoped a drug company would provide accurate information regarding a medication's risk, he acknowledged that drug risks are often minimized. *Id.* at 40:10–41:9. Because of this, Dr. Hall does not simply take information from the drug companies, but rather conducts his own research through the literature, textbooks, conferences, and review services not associated with the drugs. *Id.* at 41:16–23. He would not continue a patient on a medication unless he believed the benefits outweighed the risks for that patient. *Id.* at 103:20–104:5. Dr. Hall testified that all prescription medications have side effects. *Id.* at 107.

Dr. Hall first started prescribing antipsychotic drugs in 1984 as a resident. *Id.* at 42:12–14. Risperdal is one of the first second-generation antipsychotics. *Id.* at 43:6–14. Dr. Hall first started prescribing Risperdal shortly after it came out for schizophrenia and other conditions that can create psychosis such as bipolar disorder, schizoaffective disorder, and major depression. *Id.* at 44:11–45:2. He did not initially prescribe it for children. *Id.* at 45:9–13. When he first started prescribing Risperdal, his understanding of Risperdal's side effects was that it can cause a generalized discomfort, some involuntary movements, and tardive dyskinesia. *Id.* at 47:10–48:4. He was not certain about whether hyperprolactinemia was associated with Risperdal use when he started prescribing it. *Id.* at 49:15–23. He could not recall if he discussed the risk of gynecomastia with patients he prescribed Risperdal for in the year 2000. *Id.* at 76–78.

Pharmacy records show Dr. Hall wrote Harper prescriptions for Risperdal in March, April, May, June, July, October, and November 2000. *Id.* at 57:1–62:7, 65–66. In December 2000, Dr. Hall prescribed Zyprexa, an atypical antipsychotic, but he does not know why he switched Harper from Risperdal to Zyprexa. *Id.* at 62–63.

Dr. Hall was aware at the time that Risperdal was not approved as safe and effective for use in children, and would have taken that into account when prescribing for children and adolescents. *Id.* at 116–17. He would tell a parent when he was prescribing a medication that had not been approved for use in children and adolescents. *Id.* at 118–19.

IV. DAUBERT MOTIONS

Plaintiff challenges defense experts, Janet Arrowsmith, M.D., and Elias G. Chalhub, M.D. (Docs. 3, 5). Dr. Arrowsmith is being offered by the defense as an expert in regulatory and epidemiology matters. Plaintiff argues that Dr. Arrowsmith's opinions about what the FDA would have done had it been provided additional information are speculative and conjecture, and her

opinions regarding what the FDA did in 2014 and 2015 are irrelevant to Harper's use of brand-name Risperdal. (Doc. 4 at 5–7).

Dr. Chalhub opines on pediatric neurology matters and drug labeling. Plaintiff contends Dr. Chalhub's opinions should be excluded because they rely solely on his personal experiences, and not on any of the peer-reviewed literature he cites, which document that Risperdal causes significantly higher levels of prolactin, especially in children and adolescents, than other second-generation atypical antipsychotics. (Doc. 6 at 5–11). Plaintiff impugns Dr. Chalhub's qualifications to testify as to the adequacy of the Risperdal label and challenges his opinion that gynecomastia is "rare" as being contradictory to the facts and the medication label. *Id.* at 12–15. Lastly, Plaintiff contends Dr. Chalhub's opinion that the medication is "safe and effective" is argument and not expert testimony, and therefore should be excluded under Fed. R. Evid. 702 and *Daubert*. *Id.* at 15.

Defendant challenges Plaintiffs' experts, Dr. Michael Freeman, Dr. Laura Plunkett, and Dr. Elizabeth Naftalis. (Docs. 14, 16, 18). Defendant contends that Dr. Freeman's general causation opinion should be precluded because he failed to apply a reliable methodology, his literature review was unreliable, and the studies he relies upon do not support his theory of causation. (Docs. 14, 15). Defendant also argues Dr. Freeman's "relative risk" calculation is no assistance to a jury, cannot form part of a differential diagnosis, lacks a reliable methodology, and would be unduly prejudicial. Defendant seeks to exclude the specific and general causation opinions of Dr. Naftalis. (Docs. 18, 19). Regarding Dr. Plunkett, Defendant challenges Dr. Plunkett's regulatory and general causation opinions. (Docs. 16, 17).

V. DISCUSSION

To a significant degree, this case epitomizes the limitations of medical science, the law, and their interaction. The course of human history has seen profound improvements in our

understanding of health, disease, and other afflictions. Recent advances in diagnosis and treatment of medical conditions, both physical and mental, are often little short of miraculous. Despite these advances, our understanding of maladies and their safe and effective treatment remains incomplete and imperfect. This is especially and poignantly true with respect to the broad category of mental health conditions. Doctors and the pharmaceutical industry have developed any number of powerful medicines for treatment of many of those conditions, with varying levels of effectiveness. All these medicines carry the burden of potential side effects for some or all users. Determining the origin of adverse conditions associated with certain drugs is often difficult.

Measuring the breadth and fixing the limits of legal liability for adverse drug reaction requires development and application of legal principles in an area of great medical uncertainty and conflicting economic and societal goals. Through federal and state legislation, administrative regulation and approvals, and the common law, we establish standards for patients, doctors, and pharmaceutical companies to govern their affairs. Legal concepts of proof and causation are often not readily applied where scientific knowledge is incomplete and uncertain. The twin aims of providing appropriate compensation to individuals injured by others while encouraging doctors and drug companies to advance the field of medicine frequently conflict, as in this case.

In its motion for summary judgment, Janssen argues Plaintiff cannot prevail on any theory. First Janssen submits that Plaintiff has offered no evidence to support that the Risperdal label was inadequate, which is necessary for a claim under Alabama's Extended Manufacturer's Liability Doctrine (AEMLD). Specifically, Janssen argues the Risperdal label adequately warned as to pediatric use, Harper's physicians confirmed the adequacy of the label as to pediatric use, the label was accurate as to the potential side effect of gynecomastia, there was no evidence that required Janssen to change the label as of November 2000, and Plaintiff's label adequacy arguments are preempted by federal regulation. (Doc. 13 at 14–27). Second, Janssen argues Plaintiff lacks

evidence of the essential elements of reliance and causation, including the inability to satisfy Alabama's learned intermediary doctrine. *Id.* at 28–31. Janssen's third argument on the failure to warn claims is Plaintiff lacks sufficient evidence that Risperdal caused Harper's claimed gynecomastia. *Id.* at 32–35. Finally, Janssen contends that Plaintiff is unable to establish separate claims for wanton misconduct, breach of the implied warranty of merchantability, fraud, negligent misrepresentation or punitive damages. *Id.* at 35–40.

Plaintiff responds that disputed questions of fact regarding the adequacy of the label's warnings and whether these inadequacies caused Harper's physicians to prescribe Risperdal preclude a finding of summary judgment in Janssen's favor. (Doc. 25).

A. Failure to Warn/AEMLD Claims and the Learned Intermediary Doctrine

The gravamen of Plaintiff's claims is that Janssen failed to provide accurate or complete information about the risk of gynecomastia from Risperdal use. Plaintiff contends that Janssen significantly distorted the nature and severity of hyperprolactinemia and gynecomastia, and this, in turn, had an impact on the prescribing decisions of Harper's treating physicians. Plaintiff claims that Janssen has known since 1994 that Risperdal causes hyperprolactinemia and that the effect on prolactin levels was not the same as other second-generation antipsychotics. Plaintiff points to numerous pre-2006 Janssen studies and internal documents to support her argument that Janssen knew the risks associated with Risperdal use were significantly different from the risks outlined in the Risperdal label prior to 2006 and Janssen was negligent or fraudulent in failing to warn of those risks.

Plaintiff has sued Janssen under the AEMLD, which provides that "a manufacturer, or supplier, or seller, who markets a product not reasonably safe when applied to its intended use in the usual and customary manner, constitutes negligence as a [m]atter of law." *Casrell v. Alltec Indus., Inc.*, 335 So. 2d 128, 132 (Ala. 1976). In the context of prescription medication, the

adequacy of the warning issued by a drug manufacturer bears on whether a plaintiff has proven a prima facie case under the AEMLD. *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984). Consequently, "in the case of an 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous." *Id.* (citations omitted). To prevail on an inadequate warning claim under Alabama law, Plaintiff must establish that Janssen breached a duty which proximately caused Plaintiff's injury. *E.R. Squibb & Sons, Inc. v. Cox*, 477 So. 2d 963, 969 (Ala. 1985).

"A prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug. Once that duty is fulfilled, the manufacturer has no further duty to warn the patient directly." *Weeks*, 159 So. 2d at 673. Alabama has adopted the learned-intermediary doctrine. *See Stone*, 447 So.2d at 1304–05 (adopting the learned-intermediary doctrine in pharmaceutical products liability cases). Alabama's learned-intermediary doctrine "creates an exception to the general rule that one who markets goods must warn foreseeable ultimate users about the inherent risks of his products." *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 519 (11th Cir. 2007). Rather, the doctrine imposes on a pharmaceutical company, such as Janssen, a duty to provide warnings solely to the prescribing physician rather than to the patient directly. *Stone*, 447 So. 2d at 1304. The Alabama Supreme Court explained:

> The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and that, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient.

Weeks, 159 So. 3d at 672–73. The doctrine exists because consumers can obtain prescription drugs only through a physician or other qualified healthcare provider, and physicians are trained to

understand the highly technical warnings required by the FDA in drug labeling. *Id.* at 673 (citing 21 U.S.C. § 353(b)(1); 21 C.F.R. § 201.56). The doctrine "recognizes the role of the physician as a learned intermediary between a drug manufacturer and a patient." *Id.*

While the adequacy of a drug manufacturer's warning is measured by its effect on the physician, and not by its effect on the consumer, "if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." *Id*. For the doctrine to apply, a plaintiff must make a specific showing: "that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." *Id.* at 673–74.

Alabama's learned-intermediary doctrine applies both to actions brought pursuant to the AEMLD, *see Morguson v. 3M Co*., 857 So.2d 796, 802–03 (Ala. 2003), and to those based on a negligent failure to warn theory. *See Stone*, 447 So.2d at 1304–05. The learned-intermediary doctrine can be an absolute defense to a failure to warn claim. *Weeks*, 159 So. 3d at 673 (citing Mitesh Bansilal Shah, Commentary, *As a Matter of Fact or a Matter of Law: The Learned Intermediary Doctrine in Alabama*, 53 Ala. L. Rev. 1299, 1301 (2002)). Viewing the facts in a light most favorable to Plaintiff, Janssen knew prior to the 2006 label change that Risperdal caused potentially greater risk of increased prolactin levels than competing second-generation antipsychotics, but failed to warn prescribing physicians and consumers of that risk prior to October 2006. That said, the record evidence establishes that the pre-2006 label was not intended to be a risk profile for adolescents; the label specifically stated "safety and effectiveness in pediatric patients have not been established"; and the precaution section of the label explicitly advised that risperidone can increase prolactin levels and gynecomastia has been reported in patients taking prolactin-elevating compounds.

Plaintiff cites the Fifth Circuit's opinion in *McNeil v. Wyeth*, 462 F.3d 364, (5th Cir. 2006) for the proposition that a label that merely mentions a potential condition resulting from the medication as being "comparatively rare" when the risk of developing the condition is actually significantly higher is not only misleading, but also ineffective. (Doc. 25 at 22–25). Plaintiff argues here that Janssen's minimizing the risk of hyperprolactinemia and gynecomastia in the Risperdal label was misleading given Janssen's knowledge from studies conducted in the late 1990s and early 2000. Plaintiff points to excerpts of Drs. Mathisen and Hall's testimony to argue the effect the "misleading" Risperdal label had on Harper's prescribing physicians. Of significance, Dr. Mathisen testified he knew that pediatric use of Risperdal was not indicated. And he knew that gynecomastia was a potential side effect of prolactin-elevating compounds such as Risperdal, separate from what was contained in the manufacturer's label, and chose to prescribe the medication notwithstanding those risks. Although Dr. Mathisen stated if he had known that Risperdal elevated prolactin levels more than other second-generation antipsychotics, he would have factored that into his risk-benefit analysis and included in his discussion with patients, Dr. Mathisen acknowledges that until a study is completed and the data analyzed, it is not available for him to rely upon in making his prescribing decision. (Doc. 34-87 at 485–86). Moreover, many of the results of the clinical trials were not published until 2000 or later, and Dr. Mathisen last prescribed Risperdal for Harper in 1999. It is worth noting too that Dr. Mathisen continued to prescribe Risperdal to other children and adolescent patients even after the generic version of the medication was released.

Plaintiff has declared that she would not have consented to her son taking Risperdal if she had been advised that it could cause gynecomastia, *see* (Doc. 34-68), but this statement must be considered in light of her testimony that she permitted her son to continue to use Abilify even though one physician stated Abilify was "killing [her] son." (Doc. 34-86 at 226–28).

As for Dr. Hall, while he does not have any specific recollection of hyperprolactinemia or gynecomastia being a side effect of Risperdal, his custom and practice was to familiarize himself with the risks and benefits of medications before prescribing them, through his own independent research and review of the literature, and would review those risks and benefits with the patient or patient's guardian.

The prescribing decisions of Harper's health care providers were made after weighing the risks and benefits of the medication. Critical to a plaintiff avoiding the learned-intermediary doctrine is a demonstration "that the manufacturer failed to warn the physician of a risk *not otherwise known to the physician*." *Weeks*, 159 So. 3d at 673 (emphasis added). Dr. Mathisen testified he was aware that gynecomastia has been reported in patients receiving prolactin-elevating compounds even before the information was printed on the Risperdal label and would have factored that into his prescribing decision. Dr. Hall was aware that Risperdal's safety and effectiveness in children had not been established at the time he was prescribing Risperdal for Harper, and would have taken that into account in his prescribing decision. Drs. Mathisen and Hall testified they made their prescribing decisions after weighing the risk of Risperdal's side effects with the benefits Harper received from being on the medication.

Applying Alabama's learned-intermediary doctrine to the facts here, the court finds that Janssen provided adequate warnings to Harper's prescribing physicians such that Plaintiff's claims against Janssen under the AEMLD and for failure to warn are barred. Moreover, Harper's prescribing physicians knew use of Risperdal in children was an "off-label" use, independently knew of the risks associated with the medication or researched them prior to prescribing the medication, and chose to prescribe it anyway. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 n.8 (11th Cir. 2002) ("Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the

plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link is broken and the plaintiff cannot recover.") (citation omitted). Plaintiff argues the adequacy of the label warning is a question of fact that must be submitted to the jury. In this Circuit, however, summary judgment is appropriate when a Plaintiff's claims against a drug manufacturer are barred by the learned-intermediary doctrine. *See, e.g., Small v. Amgen, Inc.*, No. 17-11440, 2018 WL 501354 (11th Cir. Jan. 22, 2018), *Bodie*, 236 F. App'x at 522. For the reasons set forth above, summary judgment is due to be granted in Janssen's favor on Plaintiff's AEMLD and failure to warn claims on the basis of the learned-intermediary doctrine.

C. Wantonness Claim

In Alabama, the term "wantonness" is statutorily defined as "[c]onduct which is carried on with a reckless or conscious disregard of the rights or safety of others." ALA. CODE § 6–11–20(b)(3). To state a common law claim for wantonness, a plaintiff must show defendant engaged in "the conscious doing of some act or the omission of some duty while knowing of the existing conditions and being conscious that, from doing or omitting to do an act, injury will likely or probably result." *Ex parte Essary*, 992 So.2d 5, 9 (Ala. 2007) (citing *Bozeman v. Central Bank of the South*, 646 So.2d 601 (Ala. 1994)). Although Janssen's internal studies showed that gynecomastia was a potential side effect of Risperdal use, this fact was contained in the label warning and Plaintiff can point to no evidence that supports Janssen knew that gynecomastia was a *likely or probable* result of Risperdal usage.

Alabama courts have recognized that wantonness requires an "act done or omitted with knowledge of the probable consequence and with reckless disregard of such consequence." *Scharff v. Wyeth*, No. 2:10-CV-220-WKW, 2012 WL 3149248, at *3 (M.D. Ala. Aug. 1, 2012) (citation omitted). Plaintiff argues Janssen acted wantonly in actively marketing Risperdal to child

physicians prior to Risperdal having an approved indication for use by children and adolescents. (Doc. 25 at 39–42).[15] Dr. Mathisen testified, however, that he knew that Risperdal had not yet been approved for use by children when he prescribed it prior to 2006 and that the label was not intended to be a risk profile for children and adolescents. Moreover, the pre- and post-2006 Risperdal labels specifically warned of the possibility of gynecomastia. The fact that the warnings could have been broader or stronger does not equate to reckless disregard or an indifference toward safety. *See Scharff* at *9 ("Even accepting [plaintiff's] argument and evidence that Wyeth engaged in an extreme disinformation campaign, which challenged the studies, muddied the waters with less reliable industry-funded studies, underplayed the risks with dear doctor letters, and engaged in suspicious attacks on the outside studies, these acts are not sufficient to overcome the warning requirement for wanton conduct [where it was] undisputed that Wyeth [warned] … the risk of breast cancer is unknown, although a moderately increased risk [of breast cancer] in those taking combination estrogen/progestin therapy has been reported."). Even if Janssen prior to 2006 could or should have included a warning that Risperdal leads to greater increases in prolactin levels than other second-generation antipsychotics, this fact does not negate that the 1993 through 2006 labels contained a precaution specifically stating that "risperidone elevates prolactin levels and the elevation persists during chronic administration." *See, e.g.*, (Doc. 34-54 at 3). The same section identified that "disturbances such as … gynecomastia … have been reported with prolactin-elevating compounds, [although] the clinical significance of elevated serum prolactin levels is unknown for most patients." *Id.* And finally, the label explicitly stated that Risperdal had not been approved for use by children and adolescents. Perhaps the warning could have been worded

[15] Plaintiff references Janssen representatives calling on Dr. Mathisen from 2002 until 2004. (Doc. 25 at 41). These visits are irrelevant to the issues in this case where Dr. Mathisen last prescribed Risperdal for Harper in 1999 and Harper discontinued use of Risperdal in 2000.

clearer and without qualifications, but it cannot be said that it evidences an indifference toward safety. Accordingly, Janssen's motion is due to be granted on Plaintiff's wantonness claim.

D. Breach of Implied Warranty of Merchantability

Under Alabama law, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." ALA. CODE § 7–2–314 (1975). "Merchantability" refers to a product's being, in part, "fit for the ordinary purpose for which such goods are used." *Id.* These provisions in the Alabama Code mirror the Uniform Commercial Code's ("U.C.C.") provisions on the implied warranty of merchantability. *See* U.C.C. § 2–314. A plaintiff can establish a prima facie case for breach of the implied warranty of merchantability if the plaintiff can prove the existence of the warranty; a breach of that warranty; and damages proximately resulting from that breach. *Bodie*, 236 F. App'x at 522.

"In general, Alabama law does not recognize a cause of action for breach of implied warranty of merchantability for inherently dangerous products." *Barnhill v. Teva Pharm. USA*, Inc., 819 F. Supp. 2d 1254, 1263 (S.D. Ala. 2011). As the Eleventh Circuit has noted "courts applying Alabama law have seen fit to subsume U.C.C.-based breach of implied warranty claims into tort and product liability claims, where the product is fit for its intended use and there is no evidence of 'non-merchantability' other than a general allegation that the product contains inherent dangers." *Bodie*, 236 F. App'x at 524. Here, Plaintiff lacks evidence that Risperdal was not fit for its intended purpose as a mental health medicine. "[I]f the product does what it is supposed to, that product is presumed merchantable even if there are also substantial risks connected with the use of that product." *Collins v. Novartis Pharm. Corp.*, No. 2:08-CV-438-MHT-PWG, 2015 WL 178157, at *7 (M.D. Ala. Jan. 14, 2015), *report and recommendation adopted in part*, No. 2:08CV438-MHT, 2015 WL 2183700 (M.D. Ala. May 11, 2015); *see also Shell v. Union Oil Co.*, 489 So. 2d 569, 572 (Ala. 1986) ("U.C.C. does not impose upon the seller the broader obligation

to warrant against health hazards inherent in the use of the product when the warranty of commercial fitness has been complied with"). The mere presence of harmful consequences which may result from appropriate use will not render a product unfit for purposes of a claim for breach of implied warranty of merchantability. Summary judgment in favor of Janssen is therefore warranted on this claim.

E. Fraud and Negligent Misrepresentation

A review of Plaintiff's fraud and negligent misrepresentation claims in the complaint reveal the claims are based on allegations of Janssen's failure to disclose or warn of known risks of Risperdal. *See* (Doc. 34-2 at 13–69, ¶¶ 167–94). To the extent these counts are repetitive of Plaintiff's failure to warn claims, they would be barred for the reasons set forth above.

The Alabama Supreme Court has recognized, however, that plaintiffs can pursue claims for fraud and negligent misrepresentation against drug manufacturers independent of an AEMLD claim. *See Weeks*, 159 So. 3d at 656. To state a claim for fraud under Alabama law, a plaintiff must establish "(1) a false representation (2) concerning a material fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result." *Id.* The elements of a claim for negligent misrepresentation are "(1) a misrepresentation of material fact, (2) made willfully to deceive, recklessly, without knowledge, or mistakenly, (3) which was justifiably relied on by the plaintiff under the circumstances, and (4) which caused damage as a proximate consequence." *Foremost Ins. Co. v. Parham*, 693 So. 2d 409, 422 (Ala. 1997).

In a light favorable to Plaintiff, the Janssen studies revealed that the occurrence of gynecomastia could be considered "frequent" and not "rare" as referenced in the Janssen label for

Risperdal.[16] Additionally, Plaintiff claims Janssen misrepresented that prolactin elevation was a class effect when it knew, but failed to disclose, that Risperdal resulted in greater levels of prolactin compared to other second-generation antipsychotics. Even if Plaintiff can establish these facts were false or misleading, Plaintiff has failed to come forward with evidence establishing that these statements or omissions were relied upon by Harper's prescribing physicians or that they caused Harper's gynecomastia when his prescribing doctors testified they knew Risperdal was not approved for use in children and were independently aware of the risks of Risperdal and weighed those risks before prescribing the medication. Because Plaintiff is unable to establish reliance or causation, Janssen's motion for summary judgment is due to be granted on Plaintiff's fraud and negligent misrepresentation claims.

F. Punitive Damages

In order to recover punitive damages, a plaintiff must prove "by clear and convincing evidence that the defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff." ALA. CODE § 6-11-20.

As used in this provision, "fraud," "malice," "wantonness," "clear and convincing evidence," and "oppression" are defined as follows:

> (1) Fraud. An intentional misrepresentation, deceit, or concealment of a material fact the concealing party had a duty to disclose, which was gross, oppressive, or malicious and committed with the intention on the part of the defendant of thereby depriving a person or entity of property or legal rights or otherwise causing injury.
> (2) Malice. The intentional doing of a wrongful act without just cause or excuse, either:
> a. With an intent to injure the person or property of another person or entity, or
> b. Under such circumstances that the law will imply an evil intent.
> (3) Wantonness. Conduct which is carried on with a reckless or conscious disregard of the rights or safety of others.

[16] Janssen disagrees, arguing that the frequency of gynecomastia is not referenced in the precautions section of the label, and the reference to "rare" is only made with regard to a particular pre-marketing study result.

> (4) Clear and convincing evidence. Evidence that, when weighed against evidence in opposition, will produce in the mind of the trier of fact a firm conviction as to each essential element of the claim and a high probability as to the correctness of the conclusion. Proof by clear and convincing evidence requires a level of proof greater than a preponderance of the evidence or the substantial weight of the evidence, but less than beyond a reasonable doubt.
> (5) Oppression. Subjecting a person to cruel and unjust hardship in conscious disregard of that person's rights.

ALA. CODE § 6-11-20. For the reasons discussed above as to why the court found no claim for fraud or wantonness, the court similarly finds that Plaintiff is unable to satisfy the steep burden of establishing entitlement to punitive damages.

VI. CONCLUSION AND RECOMMENDATION

When a patient who is treated with a course of medication develops other medical problems, issues of causation and responsibility can arise. Was the second condition a result of the drug treatment or merely correlated or coincidental? Even if deleterious, is the second condition a proper trade-off for relief from the first condition? Though our scientific knowledge has advanced considerably, medicine cannot fully address these questions.

Not all medical issues have cures or effective treatments. Not all injuries have legal remedies. In this case, sadly, Harper suffers from life-long medical conditions that are difficult to treat and probably impossible to cure. It may well be that treatment of his underlying condition caused or contributed to a diagnosis of gynecomastia. Whether or not that is so (and we may never know) the law applicable to his circumstances affords no remedy against the manufacturer of the drug prescribed for his underlying condition. The court concludes the laws and regulations direct a finding in favor of Janssen.

For the reasons set forth above, it is the **RECOMMENDATION** of the Magistrate Judge that Defendant's Motion for Summary Judgment (Doc. 12) be **granted**.

It is further **RECOMMENDED**, if this Report and Recommendation is adopted, that the Plaintiff's Motion to Exclude Certain Testimony by Janet Arrowsmith, M.D., (Doc. 3), Plaintiff's Motion to Exclude Certain Testimony by Elias G. Chalhub, M.D. (Doc. 5), Defendant's Motion to Preclude Expert Testimony by Michael D. Freeman, MedDr, MPH, FAAFS (Doc. 14), Defendant's Motion to Preclude Expert Testimony of Laura M. Plunkett, PhD, DABT (Doc. 16), and Defendant's Motion to Preclude Expert Testimony of Elizabeth Z. Naftalis, M.D. (Doc. 18) be **denied as moot**.

VII. NOTICE TO PARTIES

A party has fourteen days from this date to file written objections to the Report and Recommendation's factual findings and legal conclusions. Accordingly, it is hereby ORDERED that any objections to the Report and Recommendation shall be filed on or before **April 18, 2018**. A party's failure to file written objections waives that party's right to challenge on appeal any unobjected-to factual finding or legal conclusion the district judge adopts from the Report and Recommendation. See 11th Cir. R. 3-1; see also 28 U.S.C. § 636(b)(1).

Respectfully recommended this 4th day of April, 2018.

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE